UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.
1:13-cv-10374-FDS

HAROLD W. HARTMAN and CATHERINE HARTMAN,

Plaintiff(s),

v.

MDL No. 2419
Master Docket No. 1:13-md-2419-FDS

Honorable F. Dennis Saylor

UNIFIRST CORPORATION, A/D/B/A UNICLEAN CLEANROOM SERVICES,

DEMAND FOR JURY TRIAL

Defendant.

AMENDED SHORT FORM COMPLAINT AGAINST UNAFFILIATED DEFENDANT

Plaintiffs Harold W. Hartman and Catherine Hartman, complaining against the Defendant, allege as follows:

FIRST COUNT

1. Pursuant to MDL Order No. 7, entered in In Re: New England Compounding Pharmacy, Inc. Products liability Litigation, Master Docket No. 1:13-md-2419-FDS, the undersigned counsel hereby submit this Short Form Complaint and Jury Demand against the Defendant, and adopt and incorporate by reference the allegations in the Plaintiffs' Master Complaint, with attachments, and any and all amendments thereto.

2. Plaintiff Harold W. Hartman is a resident of the State of Indiana.

3. Plaintiff Harold W. Hartman brings this action:

☒ On behalf of himself.

4. Additionally, Plaintiff Catherine Hartman is the:

☒ Spouse

of Harold W. Hartman, is a resident(s) of the State of Indiana, and is hereby named as an additional Plaintiff, and claims damages.

5. Plaintiffs assert that the Plaintiff Harold W. Hartman was administered New England Compounding Pharmacy, Inc. ("NECC") drug methylprednisolone acetate (hereinafter referred to as "NECC drug"), causing injuries and damages.

6. The aforesaid administration of the NECC drug occurred on: October 9, 2012 by Dr. Johnathon Schrock, at the Goshen Hospital, located in Goshen, Indiana,

7. Plaintiffs adopt and incorporate by reference the following Causes of Action asserted against the Defendants in the Master Complaint:

☒ COUNT II: NEGLIGENCE AND GROSS NEGLIGENCE (Against UniFirst)

☐ COUNT III: NEGLIGENCE AMD GROSS NEGLIGENCE (Against Clinic Related Defendants)

☐ COUNT IV: VIOLATION OF CONSUMER PROTECTION STATUTES (Against Clinic Related Defendants)

☒ COUNT VI: VIOLATION OF M.G.L. C. 93A (Against UniFirst)

☐ COUNT VII: BATTERY (Against Clinic Related Defendants)

☐ COUNT VIII: FAILURE TO WARN (Against Clinic Related Defendants)

☐ COUNT IX: TENNESEE PRODUCT LIABILITY CLAIMS (Against Tennessee Clinic Related Defendants)

☐ COUNT X: AGENCY (Against Clinic Related Defendants)

☐ COUNT XI: CIVIL CONSPIRACY (Against Clinic Related Defendants)

☐ COUNT XII: WRONGFUL DEATH PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendants)

☒ COUNT XIII: LOSS OF CONSORTIUM (Against UniFirst)

☒ COUNT XIV: PUNITIVE DAMAGES (Against UniFirst)

8. Plaintiff(s) have sent or served the pre-suit notice or demand requirements necessary to bring the claims set forth below, as required under M.G.L. C. 93A. See attached demand letter. Plaintiffs do not now assert but will seek leave to amend to assert the following claims promptly after the time period for giving notice has expired:

9. Plaintiff Harold W. Hartman claims to have suffered injuries as a result of the administration of NECC's drug as alleged by the Plaintiffs and adopted by reference in each and all of paragraphs 20 through 27 of their First Amended Complaint attached hereto.

10. Plaintiff Catherine Hartman claims to have suffered damages as a result of the administration of NECC's drug as alleged by the Plaintiffs and adopted by reference in each and all of paragraphs 54 through 56 of Plaintiffs' First Amended Complaint attached hereto.

WHEREFORE, Plaintiffs demand Judgment against the Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

Plaintiffs reserve the right to amend this Complaint to add allegations and claims against individuals or entities currently omitted (in light of the Court's order permitting a Master Complaint naming defendants affiliated with NECC and currently participating in mediation by December 20) and to add or amend allegations against Defendants named herein based, in part, on further discovery.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Respectfully Submitted,

/s/ Robert T. Sanders III

Robert T. Sanders III
Attorney Number 9-20-
rsanders@riverwalklaw.com

Attorney for Plaintiffs

SANDERS • PIANOWSKI, LLP
300 Riverwalk Drive
Elkhart, IN 46516
Telephone: (574) 294-1499
Facsimile: (574) 294-7277

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/ Robert T. Sanders III

Robert T. Sanders III
Attorney Number 9-20-
rsanders@riverwalklaw.com

Attorney for Plaintiffs

SANDERS • PIANOWSKI, LLP
300 Riverwalk Drive
Elkhart, IN 46516
Telephone: (574) 294-1499
Facsimile: (574) 294-7277

Date: December 20, 2013.

ROBERT T. SANDERS III
MICHAEL A. PIANOWSKI
MATTHEW A. YEAKEY
JASON G. WARD*
BRIAN J. CLARK
DEBORAH J. BEAVERSON*†
BRADFORD R. SHIVELY*

LINDSEY S. BRAZYS*‡§
KRISTINE A. OSTERDAY
SAULO I. DELGADO

Sanders Pianowski LLP
Attorneys at Law
300 Riverwalk Drive • Elkhart, Indiana 46516-3040
Telephone (574) 294-1499 • Fax (574) 294-7277
www.riverwalklaw.com

JAMES L. TODD (RETIRED)

*Also admitted in Michigan
†Also admitted in Florida
‡ Also admitted in Illinois
§ Registered Patent Attorney

December 19, 2013

Via Certified Mail, Return Receipt Requested

Mr. Ronald D. Croatti, President
UniFirst Corporation
68 Jonspin Road
Wilmington, MA 01887

Re: Harold W. Hartman, et al. v. New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, et al.
United States District Court, Northern District of Indiana
Case No. 3:13 CV 00007-TLS-CAN

Dear Mr. Croatti:

I represent the Plaintiffs Harold Hartman and his wife Catherine Hartman. Mr. Hartman received an injection of contaminated methylprednisolone acetate that was compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") at its facilities at 697 Waverly Street in Framingham, Massachusetts. As a direct result of being injected with the contaminated steroid, Mr. Hartman suffered a fungal infection.

UniFirst Corporation, through its operating segment or division known as UniClean Cleanroom Services ("UniFirst"), was responsible for cleaning and sanitizing NECC's facilities, but UniFirst failed, *inter alia*, to properly perform those duties and failed to use reasonable care to prevent and eliminate contamination within NECC's facilities. This letter constitutes a demand upon UniFirst pursuant to Massachusetts General Laws, Chapter 93A, § 9 ("Chapter 93A"). Please immediately provide a copy of this letter to UniFirst's insurance carrier.

Relevant Facts

In early September, 2012, Mr. Hartman developed hip and back pain which made walking difficult. On September 11, 2012, Mr. Hartman met with Dr. Johnathon Shrock at OSMC, Elkhart, Indiana. Dr. Shrock administered a steroid injection to Harold's hip on September 12, 2012 at the Elkhart OSMC clinic. This injection did not ease Harold's pain. On October 2, 2012, Mr. Hartman again met with Dr. Shrock and it was decided that Mr. Hartman would receive a steroid injection in his spine at the Goshen Hospital on October 9, 2012. This injection relieved the pain in Harold's spine, but not in his hip. At Mr. Hartman's next visit with Dr. Schrock, he was told that it often takes a second shot to fully relieve the pain; however, Dr. Schrock was not able to perform another injection, since the steroid that was previously injected into Mr. Hartman's hip was tainted.

At the end of October, 2012, an MRI was performed on Mr. Hartman at the Goshen Hospital. The MRI revealed either an inflammation or infection at the site of the steroid injection. Mr. Hartman's hip pain had increased to the point where movement was very painful and Dr. Shrock prescribed Neurontin and Vicodin; however, the pain did not subside. On November 2, 2012, Mr. Hartman was admitted to Goshen Hospital under the care of Dr. John Hawkins, Dr. Dan Nafziger and Dr. Bhagat, who also conferred with Dr. Peter Kim, a cardiologist. He was admitted to the ICU because of a drop in blood pressure and hallucinations.

After returning to his home, Mr. Hartman had no control over his bodily functions and had constant hallucinations. As a direct, probable and responsible result of having received the contaminated Medication, Harold has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial and economic loss including, but not limited to, obligations for medical services and expenses and loss of time, and other damages.

Methylprednisolone acetate is a steroid that is administered via epidural injection to patients suffering from back and/or neck pain. Until October 2012, NECC compounded methylprednisolone acetate at its facility in Framingham, Massachusetts, and NECC compounded, marketed, sold and distributed tens of thousands of vials of methylprednisolone acetate to healthcare providers across the country.

Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the cleanroom used for the production of methylprednisolone acetate. NECC and UniFirst knew or should have known of these findings. NECC and UniFirst failed to investigate those isolates and made no effort to identify those isolates, and NECC and UniFirst failed to take any corrective actions with regards to the isolates which were found. Despite these findings, NECC continued to compound, market, sell and distribute methylprednisolone acetate.

On September 21, 2012, the Centers for Disease Control and Prevention (the "CDC") was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

On its website, CDC explains that "fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus[,]" and that "fungal meningitis is rare and usually the result of spread of a fungus through blood to the spinal cord." According to the CDC, symptoms for meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis. The symptoms of fungal meningitis, according to the CDC, "are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms."

In late September 2012, NECC recalled certain lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold. NECC identified the Elkhart OSMC clinic as one of the healthcare facilities that received vials of methylprednisolone acetate that were part of the September 2012 recall.

On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts." In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

Liability

UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals. UniFirst touts its expertise to companies like NECC.

UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials UniFirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

UniFirst markets its products and services aggressively, and represents that, among other things, "[t]o help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each cleanroom at NECC's facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and thereafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included, but were not limited to, the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst. UniFirst further agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.

UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the cleanrooms UniFirst was entrusted to clean in the following ways: (i) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free protection, such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (ii) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had been moved through exterior environments, even though such equipment had not been sanitized by or cleaned appropriately, allowing contamination to occur throughout various parts of NECC's facilities; and (iii) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants - if not eliminated - would expose patients and end use consumers such as Mr. and Mrs. Cary, to contamination of products produced by NECC in its cleanrooms. Indeed, UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper, UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

Over a significant period of time, UniFirst willfully and knowingly failed to abide by regulations, laws and guidelines, including its own policies and procedures and those of NECC, set forth to protect

consumer safety in the cleaning and ongoing maintenance of NECC's facilities, including the cleanrooms. Consequently, UniFirst allowed dangerous contaminants into, and failed to eliminate these dangerous contaminants from, NECC's facilities. For instance, between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the cleanroom used for the production of methylprednisolone acetate. Moreover, Aspergillus niger was found or brought into NECC's facilities. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into NECC's facilities, including its anterooms and cleanrooms.

Unless UniFirst offers a reasonable settlement amount to resolve this matter, Mr. Hartman intends to amend his complaint to add claims against UniFirst pursuant to Chapter 93A based on the facts as summarized above.

Damages

> A plaintiff who has suffered physical injury through the fault of a defendant is entitled to recover for pain and suffering; for reasonable expenses incurred by him for medical care and nursing in the treatment and cure of his injury; for diminution in his earning power; and for such pain and suffering and such expenses and diminution of earning capacity as are shown to be reasonably probable to continue in the future. The measure of damages is fair compensation for the injury sustained.

Rodgers v. Boynton, 315 Mass. 279, 280 (1943). *Accord Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 221 (2009).

With respect to Chapter 93A claims, the following relief is provided:

> recovery shall be in the amount of actual damages . . . or up to three but not less than two times such amount if the court finds that the use or employment of the act or practice was a willful or knowing violation of said section two or that the refusal to grant relief upon demand was made in bad faith with knowledge or reason to know that the act or practice complained of violated said section two.

Mass. G. L. c. 93A, § 9(3). Additionally, a prevailing plaintiff is also entitled to reasonable attorneys' fees and costs pursuant to Mass. G. L. c. 93A, § 9(4).

As a consequence of undergoing the ordeal of being injected with the contaminated drug, Mr. Hartman suffered pain and anxiety associated with the threat of having potentially contracted a deadly illness. Mr. Hartman was also hospitalized due to the severity of the fungal infection he contracted as a direct result of being injected with the tainted steroid. Mr. Hartman has incurred medical expenses forthe necessary treatment of his fungal infection.

Mrs. Hartman also has an independent derivative claim for damages corresponding to the loss of services, society, and companionship resulting from her husband's damages. Mrs. Hartman assisted Mr. Hartman's physicians in providing the care required by her spouse. Mrs. Hartman also anguished as a result of watching her spouse of many years suffer.

Please be advised that if UniFirst or its insurer(s) fail to respond with a good faith offer of settlement within thirty (30) days of receipt of this letter, the Court may find additional violations of Chapter 93A and award reasonable attorneys' fees and multiple damages of up to three times the actual damages found at trial. *See* Mass. G. L. c. 93A, § 9(3).

Conclusion

Pursuant to Massachusetts General Law, Chapter 93A, § 9, demand is made to UniFirst to make a reasonable offer of settlement within thirty (30) days of the date of this letter.

Very truly yours,

SANDERS • PIANOWSKI, LLP

Kristine A. Osterday
kosterday@riverwalklaw.com

KAO/vlh

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA

HAROLD W. HARTMAN and CATHERINE HARTMAN Plaintiffs, v. NEW ENGLAND COMPOUNDING PHARMACY, INC., a/k/a NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE, LLC, ALAUNUS PHARMACEUTICAL, LLC, BARRY CADDEN, LISA CADDEN AND GREGORY CONIGLIARO, Individually, Defendants.	CASE NO. 3:13 CV 00007-TLS-CAN

FIRST AMENDED COMPLAINT

The Plaintiffs, Harold Hartman and Catherine Hartman, as and for their complaint for damages against the Defendants New England Compounding Pharmacy, Inc., a/k/a New England Compounding Center, ("NECC"), Ameridose, LLC ("Ameridose"), Alaunus Pharmaceutical, LLC ("Alaunus"), Barry Cadden and Lisa Cadden (collectively, the "Caddens"), and Gregory Conigliaro ("Coniglario") (collectively, the "Defendants"), allege and state that:

PARTIES

1. Plaintiffs are residents and citizens of Elkhart County, Indiana.

2. NECC is a Massachusetts Corporation with its principal place of business in Framingham, Massachusetts. At all times material herein, NECC did business in Indiana.

3. Ameridose and Alaunus are limited liability companies formed under the laws of Massachusetts with their principal places of business in Framingham, Massachusetts. At all times material herein, Ameridose and Alaunus did business in Indiana.

4. Upon information and belief, Caddens are husband and wife, registered pharmacists and officers of NECC. Conigliaro is the brother of Lisa Cadden and the president of NECC. Barry Cadden is the state listed pharmacist for NECC. The Caddens and Conigliaro conducted business in the State of Indiana by the marketing and sale of medications therein.

ALLEGATIONS COMMON TO ALL COUNTS

5. At all times material herein, NECC was a compounding pharmacy engaged in the business of mixing, producing, packaging, marketing, distributing and selling pharmacological methylprednisolone acetate (the "Medication") for use in steroid injections.

6. During the process of NECC's production of the Medication, more than 17,000 doses were tainted with at least two types of fungus: Aspergillus and Exserohilum.

7. Tainted doses of the Medication were distributed to medical providers in Indiana.

8. On September 25, 2012, NECC recalled three lots of preservative-free methylprednisolone acetate used in Medication injections. It has since recalled all of its products, and its facility and operations have been closed by state and federal officials.

9. A compounding pharmacy prepares prescriptions for patients when a drug from a pharmaceutical manufacturer is unavailable or when the patient cannot take the standard Medication because of allergies or other reasons. NECC was licensed in Massachusetts and only authorized to prepare and sell compounded Medications to specific patients for whom they had received an individual prescription request from a health care provider.

10. An investigation by the Massachusetts Department of Public Health found that compounded Medications ready for shipment by NECC "were not labeled with patient-specific identifiers, as is required under Massachusetts licensing regulations." Accordingly, NECC was acting outside its licensing authority.

11. By such operations, NECC should have been subject to FDA regulations and oversight, but NECC improperly conducted its business operations in a manner to manipulate and deceive and, thereby, attempted to avoid the duties and obligations of a mass-producing commercial drug manufacturer.

12. The tainting of the Medication was the direct, probable and responsible result of NECC's failure to properly sterilize and test products prior to distribution to medical providers.

13. NECC has a history of public health and pharmacy regulation violations, including the following:

a. Complaints resulted in state and federal inspections of the NECC facility in 2002 and 2003;

b. In 2004, the Massachusetts Board of Registration in Pharmacy alleged that NECC violated accepted standards for compounding methylprednisolone acetate and recommended three (3) years of probation and a public reprimand;

c. In 2006, NECC entered into a settlement involving a "nondisciplinary agreement" with the Massachusetts Board of Registration in Pharmacy;

d. Also in 2006, the FDA issued a warning letter to NECC, citing potential health risks arising from the production of NECC's products.

14. Upon information and belief, the Caddens and Conigliaro are the directors, officers, managers and operators of NECC. They, and each of them, directly participated in the production of the Medication and the management and oversight of the operations of NECC, including, without limitation, the marketing and sale of its products.

15. Upon information and belief, the Caddens and Conigliaro had personal knowledge of each and all of the deficiencies and violations of NECC with respect to the Medication, and they personally contributed to the injuries and damages suffered by the Plaintiffs.

16. As of October 22, 2012, the Caddens were prevented from practicing as pharmacists. In addition, on October 22, 2012, the Department of Public Health for the State of Massachusetts requested the voluntary permanent surrender of the Caddens' licenses. If the Caddens failed to comply, the Department of Public Health for the State of Massachusetts announced that it would proceed with permanent revocation of the Caddens' licenses.

17. Defendants knowingly and intentionally distributed and sold the Medication to healthcare providers of the Plaintiffs and other healthcare providers in Indiana and throughout the United States with the knowledge that they were violating accepted and recognized standards of compounding sterility and cleanliness, thereby creating an unreasonable risk of contamination and, therefore, harm to patients receiving the Medication.

18. Defendants knowingly and intentionally failed to comply with applicable state and federal law with respect to their operations. Upon information and belief, Defendants undertook such activities in order to increase profits by the mass distribution of the Medication which, in fact, was a contaminated, dangerous and potentially deadly product.

19. Defendants' conduct, as described herein, demonstrates willful misconduct, malice, fraud, wantonness, oppression, gross negligence, and a conscious indifference to consequences.

THE PLAINTIFFS' INJURIES

20. Harold Hartman is presently eighty-four (84) years of age, and at all times material herein, he has been married to Catherine Hartman.

21. In early September, 2012, Harold developed hip and back pain which made walking difficult. On September 11, 2012, Harold met with Dr. Johnathon Shrock at OSMC. Dr. Shrock administered a steroid injection to Harold on September 12, 2012 at the Elkhart OSMC clinic. This injection did not ease Harold's pain.

22. The steroid injection that was administered to Harold by Dr. Schrock at the Elkhart OSMC clinic on September 12, 2012 was supplied by NECC and is more particularly described as Methylprednisolone Acetate, Lot # 08102012@51 BUD 2/6/13. A letter from Marcy Grow-Dorman, OSMC Outpatient Surgery Center Director, dated December 14, 2012, confirming the foregoing is attached hereto, incorporated herein by this reference, and designated as Exhibit A.

23. The Medication supplied by NECC and administered to Harold on September 12, 2012 was contaminated.

24. At the end of October, 2012, an MRI was performed on Harold at the Goshen Hospital. The MRI revealed either an inflammation or infection at the site of the steroid injection. Harold's hip pain had increased to the point where movement was very painful and Dr. Shrock prescribed Neurontin and Vicodin; however, the pain did not subside.

25. On November 2, 2012, a lab test revealed that Harold's blood level had spiked to an elevated level. That evening he was admitted to Goshen Hospital under the care of Dr. John Hawkins, Dr. Dan Nafziger and Dr. Bhagat, who also conferred with Dr. Peter Kim, a cardiologist. He was admitted to the ICU because of a drop in blood pressure and hallucinations. After returning to his home, Harold had no control over his bodily functions and had constant hallucinations.

26. On November 3, 2012, Daniel A. Nafziger, M.D., M.S., who is board certified in infectious disease, examined Harold and observed that "[h]e appears to have a left sacroiliac joint that is inflamed likely from Exserohilum infection from contaminated steroids manufactured by NECC."

27. As a direct, probable and responsible result of having received the contaminated Medication, Harold has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial and economic loss including, but not limited to, obligations for medical services and expenses and loss of time, and other damages.

COUNT I (Alter Ego, Joint Venture)

28. Pursuant to the provisions of Fed. R. Civ. P. 10(c), Plaintiffs adopt and incorporate herein by reference the allegations contained in rhetorical paragraphs numbered 1 through 27 of this Complaint, as though fully set forth herein.

29. NECC, Ameridose and Alaunus were founded by Barry Cadden and Conigliaro.

30. At all times relevant hereto, Barry Cadden and Conigliaro have been owners of NECC, Ameridose and Alaunus.

31. At all times relevant hereto, NECC, Ameridose and Alaunus have shared common ownership and corporate structures.

32. At all times relevant hereto, the Caddens and Conigliaro served as directors for NECC, Ameridose and Alaunus.

33. At all times relevant hereto, Barry Cadden and Conigliaro were the only officers at NECC and the only managers at Ameridose and Alaunus.

34. At all times relevant hereto, NECC and Alaunus have maintained a principal place of business in the same commercial office building commonly known as the Waverly Business Center, on Waverly Street, in Framingham, Massachusetts.

35. At all times relevant hereto, the business purposes of NECC, Ameridose and Alaunus were similar in that each entity was engaged in the manufacture, sale or distribution of medications or other pharmaceuticals.

36. At all times relevant hereto, Ameridose and Alaunus are and were organized and operated as the alter egos of NECC, for the benefit and advantage of Defendants, and at, all times relevant thereto, NECC exercised dominion and control over Ameridose and Alaunus.

37. NECC, Ameridose and Alaunus have so intermingled their business affairs, each with the other, that NECC, Ameridose and Alaunus are the alter egos of each other.

38. At all times relevant hereto, NECC, Ameridose and Alaunus were operated as a joint venture and/or in concert with each other.

39. NECC, Ameridose and Alaunus are in substance the same, and are but the alter egos of each other, acting solely as a device to cause harm or prejudice to the creditors of the corporations.

40. Given the scope of the harm caused by Defendants, and each of them, NECC, Ameridose and Alaunus are virtually or actually insolvent and may be closing business and operations. Therefore, the officers and directors of NECC, Ameridose and Alaunus are in a fiduciary

relationship with Plaintiffs and owe a fiduciary duty to Plaintiffs and to all other creditors of Defendants.

41. The officers and directors of NECC, Ameridose and Alaunus including, but not limited to, the Caddens and Conigliaro, participated in, were aware of, and acquiesced in the deceptive and manipulative practices of NECC, Ameridose and Alaunus, as delineated in this Complaint, and are jointly and severally liable for the acts of NECC, Ameridose and Alaunus.

42. If the officers and directors of NECC, Ameridose and Alaunus, including, but not limited to, the Caddens and Conigliaro, have allowed the corporate assets to become dissipated, such conduct would be a breach of a fiduciary duty and they are therefore liable to Plaintiffs for such breach.

43. The officers and directors, including, but not limited to, the Caddens and Conigliaro, should be directed and ordered to hold the assets of NECC, Ameridose and Alaunus in trust for the benefit of the Plaintiffs and for other creditors of the Defendants.

COUNT II (Strict Liability—Defective Manufacture)

44. Pursuant to the provisions of Fed. R. Civ. P. 10(c), Plaintiffs adopt and incorporate herein by reference the allegations contained in rhetorical paragraphs numbered 1 through 43 of this Complaint, as though fully set forth herein.

45. Defendants, and each of them, placed the Medication into the stream of commerce with the actual or constructive knowledge that it would be used without testing for defect or contamination.

46. The Medication was defective in its manufacture.

47. At the time of its distribution and sale, and at all times thereafter, the Medication was unreasonably dangerous to consumers, including Plaintiffs.

48. As a direct, probable and responsible result of the defective and unreasonably dangerous Medication, Harold suffered a fungal infection resulting in extreme pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and aggravation of a preexisting condition. The foregoing losses and injuries are either permanent or continuing and Harold will suffer damages and losses in the future.

COUNT III (Negligence)

49. Pursuant to the provisions of Fed. R. Civ. P. 10(c), Plaintiffs adopt and incorporate herein by reference the allegations contained in rhetorical paragraphs numbered 1 through 48 of this Complaint, as though fully set forth herein.

50. In the event that the laws of the State of Indiana governing products liability actions are determined to be inapplicable to the Defendants, or any of them, for any reason, such Defendants are liable to the Plaintiffs under an alternative common law theory of negligence.

51. More particularly, such Defendants, and each of them, owed a duty to Plaintiffs and others similarly situated as foreseeable users of the Medication to mix, manufacture, process, market, distribute and sell it in such a way that it is reasonably safe for its intended use and free from defects.

52. In addition, such Defendants, and each of them, were negligent in manufacturing and selling the Medication by, among other things, failing to properly prepare the Medication, failing to adequately test the Medication, and failing to conduct adequate quality control procedures for the Medication.

53. As a direct, probable and responsible result of the foregoing negligence of Defendants, Harold suffered a fungal infection resulting in extreme pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment and aggravation of a preexisting condition. The foregoing losses and injuries are either permanent or continuing and Harold will suffer damages and losses in the future.

COUNT IV (Loss of Consortium)

54. Pursuant to the provisions of Fed. R. Civ. P. 10(c), Plaintiffs adopt and incorporate herein by reference the allegations contained in rhetorical paragraphs numbered 1 through 53 of this Complaint, as though fully set forth herein.

55. As a direct, probable and responsible result of the actions, conduct and liabilities of Defendants, as detailed herein, Catherine, as the spouse of Harold, has been damaged by the loss of services, society, companionship and consortium of her husband.

56. Catherine is entitled to an award of damages against Defendants for such sums as will reasonably and adequately compensate her for the injuries and losses hereinabove described.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, as follows:

A. For such sums as will reasonably and adequately compensate Plaintiff Harold Hartman for the personal injuries and losses suffered by him as hereinabove described.

B. For such sums as will reasonably and adequately compensate Plaintiff Catherine Hartman for the loss of services, society, companionship and consortium of her husband as hereinabove described.

C. For an award of punitive damages in sums sufficient to punish Defendants and deter such conduct in them and others similarly situated.

D. For an order directing Defendants to hold the assets of all the Business Defendants in trust for the benefit of Plaintiffs and for other creditors of Defendants.

E. For the costs of this action and for all further and appropriate relief in the premises.

/s/ Robert T. Sanders III
Robert T. Sanders III
Attorney Number 9-20-
rsanders@riverwalklaw.com

Attorney for Plaintiffs

SANDERS • PIANOWSKI, LLP
300 Riverwalk Drive
Elkhart, IN 46516
Telephone: (574) 294-1499
Facsimile: (574) 294-7277

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demand a jury trial on all the issues so triable in this case.

/s/ Robert T. Sanders III
Robert T. Sanders III
Attorney Number 9-20-
rsanders@riverwalklaw.com

Attorney for Plaintiffs

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300 Riverwalk Drive
Elkhart, IN 46516
Telephone: (574) 294-1499
Facsimile: (574) 294-7277

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of February, 2013, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which sent notification of such filing to the following: jkilies@lewiswagner.com; rbaker@lewiswagner.com; dcox@lewiswagner.com; kshaheed-diallo@lewiswagner.com.; and knight.anderson@tuckerellis.com.

/s/ Robert T. Sanders III
Robert T. Sanders III

OSMC™
Outpatient Surgery Center

RECEIVED
DEC 18 2012
By

December 14, 2012

Robert T. Sanders III
Sanders & Pianowski LLP
300 Riverwalk Dr
Elkhart, IN 46516-3040

Patient: Harold Hartman
DOB: 5-31-1928

Dear Robert T. Sanders III,

It is my understanding that you have requested in writing, the date, the medication name and lot number of the medication supplied by New England Compounding Center that Harold Hartman received during his procedure at OSMC Outpatient Surgery Center.

Harold received Methylprednisolone Acetate from New England Compounding Center on the following date:

September 12, 2012 Lot# 08102012@51 BUD 2/6/13

I hope this information is helpful.

Sincerely,

Marcy Grow-Dorman

Marcy Grow-Dorman
OSMC Outpatient Surgery Center Director

EXHIBIT
A